



6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

48 CFR Parts 1503 and 1552

[EPA-HQ-OARM-2015-0657; FRL-9936-63-OARM]

Environmental Protection Agency Acquisition Regulation (EPAAR); Scientific Integrity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is issuing a proposed rule to address scientific integrity requirements in the creation of a contract clause for inclusion in solicitations and contracts when the contractor may be required to perform, communicate, or supervise scientific activities or use scientific information to perform advisory and assistance services. This clause will complement the EPA scientific integrity policy to ensure all scientific work developed and used by the Government is accomplished with scientific integrity.

DATES: Comments must be received on or before **[Insert date 60 days after date of publication in the Federal Register]**.

ADDRESSES: Submit your comments, identified by Docket ID No. **EPA-HQ-OARM-2015-0657; FRL-9936-63-OARM**, at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia

submissions, and general guidance on making effective comments, please visit:

<http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Holly Hubbell, Policy, Training, and Oversight Division, Acquisition Policy and Training Service Center (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: 202-564-1091; email address: hubbell.holly@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

1. *Submitting Classified Business Information.* Do not submit CBI to EPA website

<https://www.regulations.gov> or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI, and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket.

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, Federal Register date and page number).
- Follow directions -The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) Part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language

for your requested changes.

- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. Background

The Agency's policy on scientific integrity was based on a Presidential Memorandum for the Heads of Executive Departments and Agencies, Subject Line: Scientific Integrity, Dated: March 9, 2009. The memo directs the Director of the Office of Science and Technology Policy (OSTP) to work with the Office of Management and Budget (OMB) and agencies to develop policies to ensure all scientific work developed and used by the Government is done so with scientific integrity. This proposed rule requires the Contractor to ensure that all personnel within its organization, subcontractors and consultants, that perform, communicate, or supervise scientific activities or use scientific information to perform advisory and assistance services under the specified contract, have read and understand their compliance responsibilities regarding the EPA's Scientific Integrity Policy.

III. Proposed Rule

The proposed rule amends FAR part 1503—Improper Business Practices and Personal Conflicts of Interests, Subpart 1503.10—Contractor Code of Business Ethics and Conduct, by adding EPA Acquisition Regulation (EPAAR) § 1503.1070 - *Scientific integrity* and 1503.1071 - *Contract*

clause. FAR part 1552-Solicitation Provisions and Contract Clauses is amended by adding EPAAR clause 1552.203-72 - *Scientific Integrity*.

1. EPAAR § 1503.1070 explains the basis for the section.
2. EPAAR § 1503.1071 establishes the prescription for use of EPAAR clause 1552.203-72 in all solicitations and contracts when the Contractor may be required to perform, communicate, or supervise scientific activities, or use scientific information to perform advisory and assistance services.
3. EPAAR § 1552.203-72 – *Scientific Integrity* clause states the applicability, term definitions as used in this clause, compliance requirements, reporting requirements, if a loss of scientific integrity is detected, and potential remedies.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a “significant regulatory action” under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et. seq.*

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute; unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities

include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impact of this final rule on small entities, “small entity” is defined as: (1) a small business that meets the definition of a small business found in the Small Business Act and codified at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. After considering the economic impacts of this rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, because the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives “which minimize any significant economic impact of the proposed rule on small entities” 5 U.S.C. 503 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. This action establishes a new EPAAR clause that will not have a significant economic impact on a substantial number of small entities. We continue to be interested in the potential impacts of the rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, Local, and Tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of the Title II of the UMRA) for State, Local, and Tribal governments or

the private sector. The rule imposes no enforceable duty on any State, Local or Tribal governments or the private sector. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by State and Local officials in the development of regulatory policies that have federalism implications. “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” This rule does not have tribal implications as specified in Executive Order 13175.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045, entitled “Protection of Children from Environmental Health and Safety

Risks” (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be economically significant as defined under EO 12886, and (2) concerns an environmental health or safety risk that may have a proportionate effect on children. This rule is not subject to EO 13045 because it is not an economically significant rule as defined by Executive Order 12866, and because it does not involve decisions on environment health or safety risks.

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use” (66 FR 28335 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995 (NTTAA)

Section 12(d) (15 U.S.C. 272 note) of the National Technology Transfer and Advancement Act of 1995, Public Law No. 104-113, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (February 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent

practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment in the general public.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a major rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804(2) defines a "major rule" as any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in (1) an annual effect on the economy of \$100,000,000 or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. EPA is not required to submit a rule report regarding this action under section 801 as this is not a major rule by definition.

List of Subjects in 48 CFR Parts 1503 and 1552

Environmental protection, Government procurement.

Dated: August 21, 2018.

Kimberly Patrick,

Director, Office of Acquisition Management.

For the reasons stated in the preamble, 48 CFR parts 1503 and 1552 are proposed to be amended as set forth below:

PART 1503—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTERESTS

1. The authority citation for part 1503 continues to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

2. Add § 1503.1070 to read as follows:

§1503.1070 Scientific integrity.

The EPA's policy on scientific integrity was based on a Presidential Memorandum for the Heads of Executive Departments and Agencies, Subject Line: Scientific Integrity, Dated: March 9, 2009. The memo directs the Director of the Office of Science and Technology Policy (OSTP) to work with the Office of Management and Budget (OMB) and agencies to develop policies to ensure all scientific work developed and used by the Government is done with scientific integrity. This section and clause complement the EPA Scientific Integrity Policy.

3. Add § 1503.1071 to read as follows:

§1503.1071 Contract clause.

Contracting Officers shall insert the contract clause at 1552.203-72 - *Scientific Integrity*, in solicitations and contracts when the Contractor may be required to perform, communicate, or supervise scientific activities, or use scientific information to perform advisory and assistance services. Examples of such scientific activities include, but are not limited to, computer modelling, economic analysis, field sampling, laboratory experimentation, demonstrating new technology, statistical analysis, and writing a review article on a scientific issue.

PART 1552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

4. The authority citation for part 1552 continues to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

5. Add § 1552.203-72 to read as follows:

§1552.203-72 Scientific integrity.

As prescribed in 1503.1071, insert the following clause:

SCIENTIFIC INTEGRITY (DATE)

(a) *Applicability.* This contract will require the Contractor to perform, communicate, or supervise scientific activities, or use scientific information to perform advisory and assistance services. When performing, communicating, supervising, or utilizing scientific activities or scientific information, the Contractor shall adhere to EPA's Scientific Integrity Policy.

(b) *Definitions.* "Advisory and assistance services" (see FAR 2.101).

"Scientific Activities" means those activities leading to the systematic knowledge of the physical or material world, largely consisting of observation and experimentation. It also includes the supervision, utilization, and communication of these activities.

"Scientific Information" means factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge, such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks on a web page to information that others disseminate. This definition excludes opinions, where the agency's presentation makes clear that an individual's opinion, rather than a statement of fact or of the agency's findings and conclusions, is being offered.

“Scientific Integrity” means the adherence to professional values and practices, that is, the codes of ethics and behaviors in the scientists’ fields of study, when conducting, supervising, communicating, and utilizing the results of science and scholarship. It ensures objectivity, clarity, reproducibility, and utility. It also provides insulation from bias, fabrication, falsification, plagiarism, improper outside interference, and censorship.

(c) *Compliance with policy.* Prior to beginning performance under this contract, the Contractor shall ensure that all personnel within their organization, including subcontractors and consultants, that perform, communicate, or supervise scientific activities, or use scientific information to perform advisory and assistance services under this contract, have read and understand their compliance responsibilities with EPA’s Scientific Integrity Policy. This requirement applies to any personnel that will supervise, conduct, utilize, or communicate scientific activities or scientific information. Examples of such scientific activities include, but are not limited to, computer modelling, economic analysis, field sampling, laboratory experimentation, demonstrating new technology, statistical analysis, and writing a review article on a scientific issue.

(1) Consistent with the objective of promoting a culture of scientific integrity and transparency, as discussed in EPA’s Scientific Integrity Policy, the Contractor agrees to:

(i) Produce scientific products of the highest quality, rigor, and objectivity, by adhering to applicable EPA information quality policy, quality assurance policy, and peer review policy;

(ii) Prohibit the suppression, alteration, or otherwise impede the timely release of scientific findings or conclusions;

(iii) Adhere to the Peer Review Handbook, current edition, for the peer review of scientific and technical work products generated through this contract;

(iv) Act honestly and refrain from acts of research misconduct, including publication or reporting, as described in EPA Order 3120.5 Policy and Procedures for Addressing Research Misconduct. Research misconduct does not include honest error or differences of opinion;

(v) Require that reviews of the content of a scientific product be based only on scientific quality considerations, e.g., the methods used are clear and appropriate, the presentation of results and conclusions is impartial;

(vi) Ensure scientific findings are generated and disseminated in a timely and transparent manner, including scientific research performed by subcontractors and consultants who assist with developing or applying the results of scientific activities;

(vii) Include an explication of underlying assumptions, accurate contextualization of uncertainties, and a description of the probabilities associated with both optimistic and pessimistic projections when communicating scientific findings, if applicable;

(viii) Document the use of independent validation of scientific methods;

(ix) Document any independent review of the Contractor's scientific facilities and testing activities, as occurs with accreditation by a nationally or internationally recognized sanctioning body; and

(x) Make scientific information available online in open formats in a timely manner, including access to data and non-proprietary models.

(2) To assure protection of staff supported by this contract, consistent with the objectives described in the Scientific Integrity Policy, the Contractor agrees to:

(i) Prohibit intimidation or coercion of scientists to alter scientific data, findings, or professional opinions or non-scientific influence of scientific advisory boards. In addition, employees, subcontractors, and consultants, including scientists, managers, and other leadership, shall not knowingly misrepresent, exaggerate, or downplay areas of scientific uncertainty; and

(ii) Prohibit retaliation or other punitive actions toward employees who uncover or report allegations of scientific and research misconduct, or who express a differing scientific opinion. Employees who have allegedly engaged in scientific or research misconduct shall be afforded the due process protections provided by law, regulation, and applicable collective bargaining agreements, prior to any action. The Contractor shall ensure that all employees, subcontractors, and consultants shall be familiar with these protections and avoid the appearance of retaliatory actions.

(e) *Loss of scientific integrity.* If during performance of this contract the Contractor becomes aware of an actual or potential loss of scientific integrity, the Contractor shall immediately inform the Contracting Officer and Contracting Officer's Representative with a description of the issue and any corrective action the contractor will take to mitigate the issue. The Contracting Officer and Contracting Officer's Representative will consult with the Agency's Scientific Integrity Official on all issues related to the loss of scientific integrity under this contract. The Agency's Scientific Integrity Official will advise the Contracting Officer and Contracting Officer's Representative on the appropriate remedy for any actual or potential loss of scientific integrity. The Contractor bears the primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with its own institution. However, EPA retains the ultimate oversight authority for EPA-supported research. The Contractor shall take the actions required as described in EPA Order 3120.5 Policy and Procedures for Addressing Research Misconduct when research misconduct is suspected or found.

(f) *Remedies.* The Contracting Officer will make the final decision on any remedy to an actual or potential loss of scientific integrity. Potential remedies include:

(1) Acceptance of the Contractor's proposed mitigation plan to the scientific integrity issue;

(2) Acceptance of an alternate mitigation plan negotiated by the parties;

(3) Termination for convenience, in whole or in part, if no mitigation plan will adequately resolve the actual or potential loss of scientific integrity; or

(4) Termination for default or cause, in whole or in part, if the Contractor was aware of an actual or potential loss of scientific integrity under this contract and did not disclose it or misrepresented relevant information to the Contracting Officer. Additionally, the Government may debar the Contractor from Government contracting, or pursue other remedies as may be permitted by law or this contract.

(g) *Subcontractors and Consultants.* The Contractor agrees to insert in any subcontract or consultant agreement placed hereunder which shall conform substantially to the language of this clause, including this paragraph (g), unless otherwise authorized by the Contracting Officer.

(h) *Additional resources.* For more information about the Scientific Integrity Policy, an introductory video can be accessed at: <https://youtu.be/FQJCy8BXXq8>. A training video is available at: <https://youtu.be/Zc0T7foot8>.

(End of clause)

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